CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees by outlining the steps involved in the conduct of on-site investigations of CAH's customers to obtain information regarding their potential risk for diversion of regulated drugs.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and to meet or exceed DEA's expectations of distributors that have been communicated to CAH through informal, non-binding communications.

1.3 The purpose of this procedure is also to enable investigators to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site investigations after receiving permission from Director or Vice President of Supply Chain Integrity.

2.0 SCOPE

This procedure applies when CAH determines that an on-site investigation of a DEA-registered customer is necessary to meet the objectives outlined in Section 1.0 above. The procedures outlined apply to all retail pharmacies, including chain pharmacies. The procedure also applies to PARMED retail customers and dispensing physician customers for whom the Director of Supply Chain Integrity will maintain special case notes and report formats. This document also provides the investigators the ability to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site visits.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK \l "Attachment1"]{~~HYPERLINK \l "Attachment1"~~}	Example Memo
[HYPERLINK \l "Attachment2"]{~~HYPERLINK \l "Attachment2"~~}	Example Memo

DEFENDANT EXHIBIT
CAH-WV-00747

[HYPERLINK \l "Attachment3"]{- ~~HYPERLINK \l "Attachment3"~~ }	Criteria for evaluating Large Volume Purchasers of Controlled and Monitored Substances
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"~~ }	Large Volume – Tactical and Analytical Committee Review Process

4.0 RESPONSIBILITIES

CAH Quality and Regulatory Affairs (QRA) investigators will be responsible for gathering information as set forth in this procedure using permissible methods like site visits, phone calls and email exchanges and will submit reports of investigation, case notes and supporting documentation to the Director of Supply Chain Integrity.

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC)	The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.
Case	An investigation of a customer conducted after a threshold event or after Cardinal Health learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
Case File	An individual file created within the case management system which is unique to a specific case and identified through the customer's DEA number. The file will serve as the investigative log in which all information collected regarding a specific case is to be documented.
Case Management	A manual or electronic system used by the Director to efficiently and effectively

System	monitor and manage each case.
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
Customer	Any retail pharmacy customer regulated and properly licensed in good standing with the DEA and any other agencies as required by state or federal law for the purchase of regulated drugs.
DEA	Drug Enforcement Administration.
Director	Director, Supply Chain Integrity and Regulatory Operations or his designee. Note: the Director is a licensed pharmacist.
Distrack	Cardinal Health's warehouse management system that is utilized by Pharmaceutical Distribution Centers. This is an Automated Management System (AMS) and includes information such as customer names, inventory, orders, shipments, threshold, etc.
Investigator	An individual employed by Cardinal Health to conduct on-site investigations of customers at the direction of the Director. These individuals are stationed throughout the United States. At times, other QRA employees or QRA designees will also fill this role.
PBC	Cardinal Health sales personnel. Acronym for Pharmacy Business Consultant.
Regulated Drug	Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.
SOM	Suspicious Order Monitoring
Suspicious Order	A customer's order for a: • Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency; • List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or • Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event The initial held order for a regulated drug which exceeds the threshold set for a specified licensed customer. This is created by a DEA#, Base Code and Threshold Limit combination.

Vice-President Vice-President, Anti-Diversion & Supply Chain Integrity & Sr. Regulatory Counsel or his designee. Note: the Vice-President is a licensed pharmacist.

6.0 PROCEDURE

6.1 Receipt & Assignment of Cases

6.1.1 Receipt of Cases

6.1.1.1 Threshold events are recorded in the ADC system. A QRA pharmacist evaluates each threshold event according to established procedures and when appropriate, requests an investigation within ADC using any of the appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions).

6.1.1.2 The Director automatically receives an email notification generated by ADC and updates an Excel spreadsheet.

6.1.1.3 In addition, requests for on-site investigations of licensed customers due to reasons other than 6.1.1.1 (**e.g.,** requests from the Large Volume Purchaser Periodic Review Process or Controlled Substance Regular Purchaser Periodic Review Process) are made by the Vice-President and forwarded to the Director. The Director enters these requests into an Excel spreadsheet.

6.1.1.4 The Director must enter each case into a case management system or confirm that a case has already been entered.

6.1.1.5 The investigator, upon the Director or Vice President's permission, may choose an appropriate investigative method (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence other than site-visits.

6.1.2 Assignment of Cases

6.1.2.1 The Director must assign each case to an investigator.

6.1.2.2 Field investigators are located throughout the United States and are assigned to regions specified as North, South, East-Northeast, East-Southeast, and West. Each investigator will have the primary responsibility for all cases located within their region of responsibility. The Director will generally assign cases within a

region to the investigator assigned to that region. When needed to expedite a case or to increase efficiency and effectiveness the Director will make assignments to field investigators which may be outside their assigned region.

6.1.2.3 Upon making the assignment, the Director must document the assignment of the case in the case management system and notify the investigator.

6.1.2.4 On occasion, cases will be assigned to a QRA Compliance Officer based in one of CAH's distribution centers.

6.2 Investigative Process

6.2.1 General Principles

6.2.1.1 Investigators are responsible, with the assistance of the Director when necessary, for managing their own time to effectively and efficiently schedule, plan, execute, document, and report each assigned case within the established time frames.

6.2.1.2 Cases must be worked and the on-site visit to the licensed customer completed within a reasonable period of time (**e.g.,** 45 calendar days of assignment) when feasible. A final report must be completed and submitted to the Director or Vice President within a reasonable period of time (**e.g.,** 10 calendar days of the visit). Time extensions must be approved by the Director.

6.2.1.3 Priority cases may be assigned shorter time frames by the Director.

6.2.1.4 Investigators are expected to develop and share resources and individual expertise to achieve the objectives of the entire team.

6.2.1.5 Each investigation is divided into four basic parts: (1) initial case preparation; (2) background investigation; (3) site visit; and (4) preparation of reports.

6.2.1.6 Each of the four basic parts to the investigation must be documented by the investigator in the case file.

6.2.1.7 The Director must monitor the progress of cases and provide guidance and direction as necessary to develop and move the case to a successful conclusion.

6.2.2 Initial Case Preparation

6.2.2.1 Investigators are responsible for maintaining a current list of open cases assigned to them by the Director.

6.2.2.2 Following the general principles, investigators will select the cases for the next

round of facility visits. This decision process should include the age of the event, priority set by the Director, and proximity of pharmacies to one another.

6.2.2.3 Gather and review the information possessed by CAH regarding the case and the licensed customer. Depending on the case and customer, this may include, but is not limited to, information located in the following systems.

a. SOM / Anti-Diversion Centralization system information
b. Data from Tableau Reports generated from customer purchase history
c. Review activity of Controlled Substance (CS) drug identified in site visit request along with activity of all CS drug family to ascertain the need for closer look at those CS drugs
d. Content Manager (either through ADC or directly from Content Manager)
e. Distrack or any other relevant source

6.2.2.4 Develop a background research plan based upon the information obtained from CAH resources and personal investigative background and instincts. This background research should include the following.

a. Verification of customer licensing (DEA, Board of Pharmacy, etc.) information.
b. Review of threshold events and comments from the QRA Pharmacist requesting the site visit if appropriate and available.
c. Speaking with the QRA pharmacist requesting the site visit if deemed necessary.
d. Obtaining information about the customer from the PBC if appropriate.
e. Review of customer responses to questionnaires.
f. Review of previous decisions regarding shipment to the licensed customer.

6.2.2.5 Document relevant results of the initial case preparation rather than the process of case preparation within the appropriate case file. A sample of appropriate relevant results that can be included in the documentation of case preparation are:

a. Verification of the pharmacy's DEA registrant number and the classes of scheduled drugs the pharmacy is currently authorized to dispense.
b. State licensure verifications of both the pharmacy and the PIC/Owner.
c. Results of any other relevant internet research.
d. Tableau report analysis/summary providing the reader of the report a solid, factual, statistical analysis of the customer.
e. A statement concerning the ratio of controls to non-controls purchased.
f. The top 3 controlled drugs purchased and their strengths.
g. Total quantities and monthly averages for select drugs, usually the drug(s) of interest to the site visit.
h. A summary of the Tableau report analysis for the final ROI for readily

comparing and contrasting the Tableau data analysis to the pharmacy dispensing report analysis.

6.2.3 Background Investigation

6.2.3.1 Create a site visit schedule and make travel arrangements.

6.2.3.2 Follow through on the research plan to gather and review outside information and/or to verify information contained in CAH records.

6.2.3.3 Identify useful internet resources to conduct background and licensure information searches for the pharmacies and their employees. When appropriate, identify useful information on identified local physicians, identified local health care facilities, and obtain geographical or other relevant information.

6.2.3.4 Research, identify and/or verify:

a. Any disciplinary actions taken by licensing agencies taken against any of the licenses issued to the facility or to any of the owner/employees of the licensed customer; and
b. Any civil or criminal actions documented by federal/state/municipal courts or any other entity which permits access to public records that have been filed against any of the licensed customers, their employees, identified local physicians, or any other person associated with the facility.

6.2.3.5 Conduct an Internet search for any evidence that the facility has an Internet presence and to determine any adverse news story for the pharmacy, pharmacist, and known top prescribers of that pharmacy, if known.

6.2.3.6 Useful Internet resources will vary depending on the case itself as well the availability of the Internet site at any given time. Some potentially helpful Internet resources include the following:

a. Google
b. Reverse address and phone directory
c. Location photographs from Google Earth or Yahoo Maps
d. Wikipedia (city information)
e. Global Internet Management (DEA # verification)
f. Secretary of State (Corporate information)
g. Department of Health
h. State Board of Pharmacy
i. ZABA Search (personal information)

6.2.3.7 Personal contact with local, state, or federal agencies or law enforcement organizations may be necessary. Such contact must be approved by the Director.

6.2.3.8 Document this background investigation within the appropriate case file.

6.2.4 Investigator Contacts for On-Site Visits

6.2.4.1 When conducting a full site visit, approximately one week prior to an on-site visit, the investigator must communicate with an appropriate representative of the licensed customer to discuss the purpose of the visit and to set a date and approximate time for the visit. The contact person for a retail independent pharmacy is usually the pharmacist-in-charge or the owner of the pharmacy.

6.2.4.2 The PBC assigned to the licensed customer should also be contacted and provided the opportunity to be present during the visit. The PBC may also assist the investigator with setting up the visit (6.2.4.1).

6.2.4.3 In preparation for a full site visit, where possible and available, the investigator can choose to request from the pharmacist-in-charge (through the PBC or Sales Point of Contact where necessary) data that may include some or all of the following:

a. A list of the pharmacy's overall top 5 prescribers of controlled substances, with DEA numbers.
b. A list of the current pharmacists, with license numbers, who are regularly employed at this location.
c. A list of all nursing homes; assisted living facilities; group homes; hospices, that the pharmacy is currently servicing and an estimate as to the number of beds/patients being serviced at each location.
d. It is preferable if a computerized generated report can be provided to ascertain the following information, but if not, an estimate will suffice; over the past 30 days, overall, what percentage of customers pay cash for their prescription medications, this includes both controls and non-controls; of that overall percentage, what part of that percentage is for controlled substances (C-II thru C-V); finally, how is the controlled substance percentage then divided between C-IIs and all C-III-Vs combined (these two percentages should equal 100%); Cash paid = prescriptions filled that are NOT paid for in whole or in part by a third-party plan such as Medicaid, Medicare, private insurance, etc. Specifically, the patient pays for the full amount of the prescription on their own using cash, debit card, credit card or check.
e. A summary drug dispensing or usage report for all controlled substances (C-II thru C-V) dispensed over the past 3 months. This report should list total quantities dispensed by dosage units for each drug name and dosage. The report should not contain any patient specific information and, when feasible, not contain prescription specific dispensing information such as quantity per prescription.
f. If possible and available, a prescription count report that lists the top

prescribers of controlled substances (C-II thru C-V) by number of controlled substance prescriptions filled by the pharmacy for these prescribers over the past 30 days. The report should not contain any patient specific information.

g. If possible and available, the number (or range) of dosage units of controlled substances normally prescribed by each of the top 5 prescribers per prescription.

6.2.5 Site Visit

6.2.5.1 Data Collection Worksheets - Information collected during a site visit should be documented on a data collection worksheet which may be unique to the type of facility being visited and the level of visit being performed. Information collected on the data collection worksheet will serve as the basis for documentation of the visit in the case file.

6.2.5.1.1 The data collection worksheet is not all inclusive and should merely be used as a guide to collect uniform data applicable to the licensed customer. Investigators should be observant and are expected to include any additional information obtained which may assist in meeting the objectives identified in Section 1.0 of this procedure.

6.2.5.2 Potential Indicators of Diversion - Investigators should be particularly alert during the on-site visit to any potential Indicators of diversion. Indicators noted during the visit must be documented in the final data collection worksheet or memo and placed in the appropriate case file. Some indicators of potential diversion include the following:

a. Customers of the licensed customer exhibit drug seeking behaviors.
b. Customers coming to the pharmacy in groups to fill prescriptions (**e.g.,** groups of younger customers who appear to be familiar with one another, groups of people from outside the local area). Reports should be specific rather than general (**e.g.,** "4 males appearing to be in their twenties arrived in one vehicle and presented prescriptions to the pharmacy" rather than "a group of young males were observed filling prescriptions.").
c. Pharmacy customers who appear to be from outside the reasonable drawing area for the facility.
d. Evidence of illicit drug use around the facility (**e.g.,** used syringes, empty prescription containers).
e. Mailing materials or other evidence of operation of an Internet pharmacy.
f. High ratio of prescriptions for regulated drugs versus other drugs.
g. High ratio of regulated prescription drug stock to other prescription drug stock.
h. High ratio of particular strengths of drugs known to be widely abused.
i. Small or non-existent front end (non-prescription) drug stock.

j. Primarily cash transactions for regulated drug prescriptions.
k. One employee responsible for the ordering, monitoring, and invoicing of products.
l. High number of customers compared to their peers.
m. Lack of auditing processes around purchases.

6.2.5.3 **Area Scan** - Upon entering the community or immediate area of the licensed customer being visited, investigators should observe and document the surroundings and note any specifics which relate to the business practices, volume of business, and type of business of the licensed customer. These include, but are not limited to, the following:

a. Types and number of health care facilities located within the area.
b. Number and types of medical practices, especially noting those who have characteristically been heavy prescribers of controlled substances, such as, pain clinics, orthopedics, surgeons, oncologists, cancer centers, weight loss clinics, etc.
c. Unusually large numbers of individuals in the general vicinity of a physician's practice or of the facility.
d. General economic condition of the area in a factual manner (without speculation or subjective commentary.

6.2.6 **Setting the Tone for the Visit**

6.2.6.1 Investigators have no authority to require compliance with any request. Our ability to look at documents or to obtain information on-site is entirely dependent on the goodwill of the licensed customer. If the level of site visit requires contact with the pharmacy personnel, it is incumbent on the investigator to enter and approach appropriate personnel and immediately attempt to establish a good rapport with the customer. Our communicated intent should be to better understand the customer's business so that CAH can partner with the customer to identify and prevent diversion of controlled substances while providing superior service to our customers.

6.2.6.2 Be prepared to discuss how the Know-Your-Customer process works and attempt to answer simple and general questions regarding our process. However, do not discuss specific threshold levels. If unable to answer a question accurately, advise that you will obtain the information and get back to the customer. Contact the Director for guidance. For questions outside our area of responsibility and knowledge, attempt to have the customer pose the question to their PBC. If unable to do so, the investigator can forward the question to the PBC. If unsure how to proceed, contact the Director for guidance.

6.2.6.3 Remember, we are a guest of the licensed customer while in their facility and they may refuse to permit or provide one or more of your requests. The

investigator must not threaten or coerce the customer in an attempt to achieve compliance with the request. If there is a refusal which cannot be resolved and it is an important element of our fact gathering, the investigator should advise that the refusal may be considered in making decisions on the sale of controlled substances and other drugs of interest including other monitored drugs to the customer. If still refused, proceed with the visit to the extent permitted, but document the refusal in the case file.

6.2.7 Interview

6.2.7.1 If the level of site visit requires an interview of pharmacy personnel, the investigator should attempt to conversationally interview the appropriate personnel representing the licensed customer. The investigator should document the name and title of the person providing the information. The purpose of this interview should include the following:

a. Completing to the extent possible the data collection worksheet for the facility.
b. Obtaining additional information when responses reveal other areas of potential concern.
c. Attempting to resolve any issues which became evident during the initial preparation and background investigation including customer responses to questionnaires.
d. For facilities containing sterile areas, investigators must make the decision if they feel they need to go into the sterile area. Base the decision on criteria such as visibility into the sterile areas.

6.2.7.2 The investigator should be aware of any non-verbal cues or activity that indicates nervousness or potential deception (**e.g.,** failure to make eye contact, hesitation to provide routine information, nervous body movements, etc.).

6.2.7.3 If information is obtained during the site visit that is inconsistent with data obtained before, during or after the site visit, the investigator should note this in the final report.

6.2.8 Tour of the Facility

6.2.8.1 If the level of site visit requires a tour of the facility, the tour should include ALL areas of the facility. Ask for permission to take photographs of the facility. It is suggested that the investigator obtain photographs of:

a. the front of the prescription department;
b. the front end non-prescription drug section(s);
c. several prescription bays or shelves;
d. back room;
e. any automation; and

f. front of the facility from the outside

6.2.8.2 Use extreme care if photographs are taken of any indicators of diversion. DO NOT put yourself at risk. If the investigators believe that photographing indicators of diversion may jeopardize the investigator's safety, note with specificity the indicators of diversion, but do not photograph. Download all digital photographs to the case file.

6.2.9 Requesting Utilization Reports

6.2.9.1 If the level of site visit requires obtaining a drug utilization report, investigators should request one. Request that the report be prepared and sent electronically rather than hard copy or fax. Unless circumstances warrant otherwise, request drug utilization reports with the following characteristics:

a. Includes a summary of all controlled substances by drug and showing total quantity dispensed or administered during the time period.
b. Includes 3 months of usage data by month.
c. Data comes directly from the facility's computer system.
d. Does not include non-controlled drugs unless specifically requested.

6.2.9.2 Request that the submission include the complete facility name, address, phone number, DEA #, and contact person.

6.2.10 Investigative Analysis of Utilization Reports - How to Submit

6.2.10.1 The investigator will conduct an analysis of the summary dispensing report which includes the common drug families of concern. Usually this will include an analysis of the drug families Oxycodone, Hydrocodone and Alprazolam but may vary over time and region of the county. In addition, the investigator should add other drug families considered problematic for the particular case based on the preparation/background work, intelligence received, or direct observation.

6.2.10.2 The analysis will establish the average quantity dispensed per month for each of the drugs families analyzed.

6.2.10.3 Where appropriate, the investigator should also analyze specific dosage forms and strengths within certain drug families (**e.g.,** Oxycodone 30 mg products).

6.2.10.3.1 Individual results pertinent to the investigation will be documented in the final report.

6.2.10.3.2 The customer's summary dispensing report and the completed analysis will be placed in the case notes.

6.2.11 Final Report

6.2.11.1 Prior to preparing the final report, the investigator must research and confirm to the extent possible any additional information received during the on-site visit to the licensed customer.

6.2.11.2 The investigator must analyze the information collected and documented in the case file and formulate an assessment for presentation to the Director. The investigator's assessment must begin with the objective criteria set forth in [HYPERLINK \l "Attachment3"]{ HYPERLINK \l "Attachment3" }. However, the investigator is free to use aggravating or mitigating considerations to provide an assessment derived from the objective criteria. Those aggravating or mitigating considerations must be appropriately articulated in the investigation report. The objective criteria are not the only factors that are to be considered as other facts and circumstances may indicate that diversion is likely or unlikely. The objective criteria are to be used as the starting point for the investigators assessment, but do not mandate the final assessment to be given. Investigators should consider all available facts and use their knowledge of pharmacies and diversion methods and trends and their professional judgment in making an assessment.

The options for the investigators assessment are:

a. Re-evaluate the customer after 12 or more months – if the facility does not currently present a significant risk for diversion; OR
b. Re-evaluate the customer after 3 months – if the facility does not currently present an immediate risk for diversion but may need to be re-evaluated after 3 or more months; OR
c. Re-evaluate the customer immediately – if the facility data or investigation warrants additional review by a senior member of the Anti-Diversion Supply Chain Integrity Leadership Team or the Large Volume Tactical and Analytical Committee.

6.2.11.3 The investigator must prepare a final report in the form of a memo (see [HYPERLINK \l "Attachment1"]{ HYPERLINK \l "Attachment1" } and [HYPERLINK \l "Attachment2"]{ HYPERLINK \l "Attachment2" }.) For objective criteria table see [HYPERLINK \l "Attachment3"]{ HYPERLINK \l "Attachment3" }

6.2.11.4 At a minimum, the memo must contain the name, DEA number, city, and state of the facility in the subject line. The body of the memo will contain:

a. An opening paragraph providing the date of the visit and the principle

individuals participating in the visit;
b. A summary of the findings in bullet point form, both positive and negative, considered in making the recommendation;
c. The assessment.

6.2.11.5 Findings bulleted in the final report should consist of a summary of the findings documented in the case file. Details should remain in the case file for review unless necessary to provide a proper perspective for the recommendation.

6.3 Analysis & Decisions

6.3.1 The Director must conduct a thorough, final review of each case and make a determination whether the case is complete and provides the information necessary to support an assessment of whether or not the customer needs to be re-evaluated by senior member(s) of the Anti-Diversion team immediately. The investigator will be contacted if necessary to clarify issues or to address questions regarding the case, the reports, and the assessment.

6.3.2 The Director must document within the case management system an approval of the assessment of the investigator. In the event that the Director comes to a different assessment, documentation must be made as an addendum to the final report with justification for the different assessment.

6.3.3 Once a final assessment has been made, a decision regarding whether to continue to supply regulated drugs to the customer must be made and appropriate follow-up steps initiated.

6.3.3.1 A decision to continue the sale of regulated drugs to the customer requires an evaluation of the customer's threshold limits for regulated drugs and adjustments when supported by findings documented in the case. The Director, or a QRA designee, must conduct such an evaluation and adjust thresholds appropriately.

6.3.3.2 A decision to discontinue the sale of regulated drugs to the customer requires the termination of the customer from the CAH system and notification to state and federal regulatory bodies.

6.3.4 If the customer was identified for site visit as a large volume purchaser as part of the Large Volume – Tactical and Analytical Committee Periodic Review Process (see SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"~~ }), the report will be submitted to that committee for final decision.

6.4 Types of Visits

6.4.1 The type of site visit to be conducted will be determined by the Director, the Vice President, or the committee requested the site visit.

6.4.2 Reconnaissance Visit - A reconnaissance visit is a site visit that does not require contact with pharmacy personnel or collection of documents or information from the pharmacy. This type of visit does not require advance coordination with the customer. The visit is intended to provide CAH with general information about the customer. This type of visit allows visibility of the customer's business without providing advance notice to the customer. In some cases, when significant information is already known about the customer and the customer's anti-diversion controls, this type of visit provides additional insight into the customer. Sections 6.2.6 through 6.2.9 do not apply to this type of visit. Portions of other sections of this SOP may not apply depending upon the availability of information collected prior to the reconnaissance visit.

6.4.3 Full Site Visit - A full site visit generally consists of all elements set forth in this SOP. However, the investigator may use sound judgment in determining the necessity and extent of specific investigative steps and inquiries.

6.4.4 Investigation other than by Site Visit – When appropriate, means of conducting a due-diligence other than by a site visit (**e.g.,** data requests, phone interviews, email interactions) may be chosen by the investigator only upon express written consent (**e.g.,** via email) from the Director. The Director must use his or her professional judgment to approve or disapprove the request and may choose to elevate the request to the Vice President of Supply Chain Integrity for a decision. Alternate means of investigation may also be used to augment a site visit.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Investigators should avoid language that is speculative or subject to multiple interpretations in the reports and case notes.

7.1.2 The findings must be based on factual data, site visit observations and analysis of data gathered prior and during site visits.

7.1.3 Where appropriate and available, analysis of dispensing data, tableau data and other information must be documented in the case notes or threshold analysis files.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

Attachment 1

Cardinal Health
7000 Cardinal Place
Dublin OH 43017

CardinalHealth

Date	03/21/12	
To	File	
From	CAH Investigator	
Subject	Morse's Magnificent Pharmacy Austin, TX	AM0284XXX

This pharmacy was visited on March 10, 2012 by CAH Investigator YYY, SCI-QRA, CAH;
Met with John Doe, R.Ph, PIC/Owner. Site visit requested based on a customer due diligence exercise for select Medium and High Volume Customers OR held order review request from SCI Pharmacist Team; this customer is considered a medium volume customer for Oxycodone products; 161,500 Oxycodone units were purchased during a six month period, May through October 2011.

Findings

- Location/Area – Pharmacy is located on a well traveled street, in a suburban mixed business and residential area; it is located in the North Stafford Medical Park; there are several medical offices and an urgent care/primary care facility also located in the park
- Ratio of controls to non-controls dispensed is 25%
- Another wholesaler has recently refused to sell controlled substances to this pharmacy based on high volume of purchases
- The top prescriber of controlled substances, primarily oxycodone products, routinely prescribes quantities of controls in the 300-400 unit range per prescription
- Practitioners identified by the pharmacy as their primary prescribers of controlled substances all held active medical licenses and current DEA registrations
- No evidence of internet prescription sales or mail order service
- Percentage of cash sales involving controlled substances was reported as 4.4%
- Large number of walk-in customers were observed, and they appeared to be consistent with the local general demographics; nothing unusual was observed
- An average of 250 prescriptions are filled daily
- A summary drug utilization report was requested, received and analyzed; a copy was provided to QRA Anti-Diversion

Investigator Assessment

Based on the evaluation criteria provided, this pharmacy needs to be

ON-SITE INVESTIGATIONS

o Re-evaluate immediately
x Re-evaluate after 3 months
o Re-evaluate after 12 or more months

However, there are mitigating factors based on facts – (1.), (2.), (3.) – that may justify re-evaluating this pharmacy after 12 or more months

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Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

Attachment 2

Cardinal Health
7000 Cardinal Place
Dublin OH 43017

CardinalHealth

Date	03/15/12	
To	File	
From	Cardinal investigator	
Subject	Wonderful Care Pharmacy Lubbock, TX	AG376XXX

This pharmacy was visited on March 10, 2012 by Cardinal Investigator, Cardinal Health. Met with Tony Jones, Pharmacist-in-Charge. Report of controlled substance dispensing was not provided during visit and is pending at the time of this report. An addendum will be filed when the dispensing report is provided by the pharmacy.

Findings

- Location/Area –Located in a strip mall, surrounding by many stores on a busy four lane street, next to an intersection//Only 10% of the pharmacy business is from walk ins and prescribing physicians in the area//pharmacy delivers to a large number of assisted living facilities (ALF) in the San Diego area//bubble packs all medications at the pharmacy for delivery to these facilities//CAH distract lists this pharmacy as a managed care, closed door pharmacy but there is also some retail business
- Dispensing data was not requested
- Clonazepam continues to be a largely prescribed drug at the ALFs.
- No evidence of mail service or internet prescription sales//majority of business is delivered to ALFs
- The pharmacy had insignificant business dispensing OTC drugs
- Store was closed at the time of the visit, which was at 7:00 a.m.
- Mr. Owner declined permission for photographs to be taken of the store

Investigator Assessment
Based on the evaluation criteria provided, this pharmacy needs to be

x Re-evaluate immediately
o Re-evaluate after 3 months
o Re-evaluate after 12 or more months

This is a unique situation which may warrant further evaluation. At this time the assessment is "Re-evaluate Immediately" based on the "*Criteria for Re-evaluate immediately - after 3 months - after 12 or more months Risk Assessment*" chart. Mitigating factors recommended for consideration in the final evaluation include:

1. The percentage of controlled substances filled as cash is affected by two factors: sale of compounded hormone products and providing service to uninsured clientele.
    i. Compounding of hormones include products containing testosterone. The pharmacy has a full compounding lab and markets their compounding services. Due to a lack of other compounding providers in Northwest Texas and Eastern New Mexico, the pharmacy services a large geographical area. Due to the volume of these medications shipped into New Mexico, the pharmacy is licensed in New Mexico as a non-resident pharmacy. It is common practice for compounders to charge cash for compounded medications due to lack of coverage or inability to adjudicate claims to third party payers.
    ii. Owner stated that the Lubbock area has a higher than average population without prescription insurance coverage. These customers will utilize other pharmacies for any medications on the $4 prescription list and trade with Caprock for all other medications. I witnessed an occurrence of this during my visit-an elderly man brought in a Schedule II prescription and I overheard his discussion with the technician that he could not afford the medication at Walgreens.
2. The Pharmacy Business Consultant did not make contact with this client with sufficient notice for him to print reports or familiarize himself with statistics for his facility. His answers were approximations. Full consideration should be reserved until information regarding his dispensing is obtained. I did request reports, but have not yet received the information.

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Attachment 3

Objective Criteria	Re-evaluate immediately	Re-evaluate after 3 months	Re-evaluate after 12 or more months
Majority Source of Controlled Substance Patients	2 Prescribers	3-5 Prescribers	>5 prescribers
Total prescriptions filled per day	<100	100-200	>200
Patients per day per prescriber	>40	20-40	<20
Cash sales for all products	>30%	20-30%	<20%
Share of Controlled Substances Units*	>20%	15-20%	<15%
Number of Wholesalers (other than CAH) if more than 10% of controlled substances are purchased from other wholesalers	>3	2 or 3	1

*Based on estimated percentages of dispensed controlled substances from customer interviews and/or summary usage reports

This criteria table is used ONLY for Large Volume Purchasers identified by the Large Volume – Tactical and Analytical Committee for site visits (per SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }). The assessment is based on one or more criteria being met by the customer at the time of the visit. The investigator is free to use aggravating or mitigating considerations to provide an assessment other than the assessment set forth in the objective criteria. Those aggravating or mitigating considerations must be appropriately articulated in the investigation report. The objective criteria are not the only factors that are to be considered as other facts and circumstances may indicate that diversion is likely or unlikely. The objective criteria are to be used as the starting point for the investigators assessment, but do not mandate the final assessment to be given. Investigators should consider all available facts and use their knowledge of pharmacies and diversion methods and trends and their professional judgment in making an assessment.

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ON-SITE INVESTIGATIONS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Steve Morse PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
2962	12 Apr 2012	Scheduled Review	Yes	Corporate	COs & DOs Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the on-site investigation process.					
Change Description and Justification					
Scheduled review. Complete rewrite of entire procedure to conform with current Cardinal Health practices. Updated document to coincide with PDQRA formatting criterion.					